From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION

(PCT Rule 66)

To:
MANDRAGOURAS, Amy E.
Lahive & Cockfield
60 State Street
Boston, MA 02109-1875
ETATS-UNIS D'AMERIQUE

ENTERED
DOCKETED
8 May 7 1997 Resp. to First Written Opinion

Date of mailing *(day/month/year)*	07.02.97
Applicant's or agent's file reference: RPI-035CPPC	REPLY DUE within 3 months/days from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 96/06200	02/05/1996	04/05/1995

International Patent Classification (IPC) or both national classification and IPC
C12N15/87

Applicant
UNITED STATES OF AMERICA AS REPRESENTED... et al

1. This written opinion is the first (first, etc.) drawn up by this International Preliminary Examining Authority.

2. This report contains indications and corresponding pages relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV [ ] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [ ] Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

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LAHIVE & COCKFIELD
FEB 11 1997

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 04/09/1997

Name and mailing address of the IPEA/
European Patent Office
D-80298 Munich
Tel. (+49-89) 2399-0, Tx: 523656 epmu d
Fax: (+49-89) 2399-4465

Authorized officer: BY
Examiner: R. Großkopf

Formalities officer (incl. extension of time limits): C. Vullo
Telephone No. 2852

I. Basis of the opinion

1. This opinion has been drawn up on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".):

[x] the international application as originally filed.

[ ] the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,

[ ] the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,

[ ] the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,

2. The amendments have resulted in the cancellation of:
[ ] the description, pages _____.
[ ] the claims, Nos. _____.
[ ] the drawings, sheets/fig _____.

3. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims _____
	Claims 1,19
Inventive Step (IS)	Claims _____
	Claims 2-18, 20-21
Industrial Applicability (IA)	Claims _____
	Claims _____

2. CITATIONS AND EXPLANATIONS

1. A method for transfection of T cells with a nucleic acid molecule comprising a gene wherein the T-cells are contacted with a stimulatory agent prior to the transfection is already described in D1 (WO 94/29436; see e.g. page 21. section II).
Therefore, at least the general methods according to present Claims 1 and 19 are not novel (Article 33.2 PCT).
Moreover, and without going into detail, nearly all of the other embodiments of the dependent claims are also disclosed in D1 (i.e. especially the use of two different agents and several of the specific agents referred to in the dependent claims) and, consequently, said claims lack novelty.

2. A detailed examination of novelty and inventive activity of the dependent claims, however, at present has not taken place for the following reasons:

First, it appears as if an inventive concept of the present application which is based on the choice of the order of the stimulation and the transfection step, is no longer present. In view of this observation, also none of the features of the dependent claims (novelty provided) can re-establish an inventive activity.

Second, in view of the lack of novelty of the main claims, most of the dependent claims become "quasi-independent" and are, regardless the absence of any inventive activity, no longer connected between each other by a common inventive concept.
Thus, in absence of one independent main claim which is, at least, novel the remaining set of claims lacks unity. Consequently, a further examination can only take place either if a decision has been taken by the Applicant which of the features of the dependent claims should be examined (e.g. by integrating this feature into a new main claim), or if one or more examination fees have been paid for each of the features which is desired to be examined.

3. For the assessment of the present Claims 19 to 21 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but will allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.